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| 10/567,459 | 07/21/2006 | Henry William Lupton | Q92794 | 9156 |
| 23373 7590 04/07/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 | | | | |
| EXAMINER | | | | |
| DOUGHERTY, SEAN PATRICK | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3736 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,459

Applicant(s)

LUPTON, HENRY WILLIAM

Examiner

SEAN P. DOUGHERTY

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-97 is/are pending in the application.
- 4a) Of the above claim(s) 81 and 94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76-80, 82-93 and 95-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date 02/07/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This is the initial Office action based on the 10/567459 application filed 07/21/2006. Claims 76-97 are currently pending and have been considered below.

Priority

This application is a 371 of PCT/IE04/00107 filed 08/09/2004. Receipt is also acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 02/07/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

The amendments filed 02/06/2009 have been considered by Examiner.

Examiner acknowledges the amendments to claims 77 and 89 and new claims 96 and 97.

Election/Restrictions

Claims 81 and 94 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/06/2009.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

The following claims are objected to because of the following informalities:

- (a) It appears the same limitations are repeated twice in lines 5-11 of claim 78;
- (b) All instances that state "and alternatively" and should state --or alternatively--;

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 78, 81-85, 90, 91 and 95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "advantageously" and "preferably" in the claims are relative terms which renders the claims indefinite. The terms "advantageously" and "preferably" are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Examiner notes that the terms "advantageously"

and "preferably" are terms generally not found in patent applications filed in the United States.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

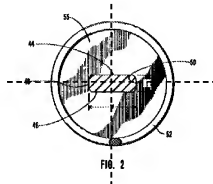
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 76, 78-80, 82-84, 86-88, 90-93 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,957,865 to Backman et al. (Backman).

Regarding claims 76, 87 and 88, Backman disclose a elongated guidewire 10 in combination with a catheter (see title) for accessing a remote site in a subject, the elongated guidewire defining a longitudinally extending central axis through the center of step 31 extending axially between a distal end 22 and a spaced apart proximal end 14, a distal portion of the guide wire adjacent the distal end along section line 2--2 being of substantially rectangular transverse cross-section best seen in Fig. 2 defining a pair of spaced apart major surfaces (w), and a pair of spaced apart minor surfaces (t) extending between the major surfaces. Backman discloses a central major plane and a central minor plane as illustrated by the dashed lines below in Fig. 2. Furthermore, Backman discloses where the rectangular transverse cross-section of the distal end 22 is capable of being pre-bent into a desired orientation (col. 6, lines 36-45). Therefore, the distal end 22 is capable of being bent into a curved configuration in the central major

plane for forming an alignment portion (meaning, the distal end 22 is bent left or right in the orientation seen below in Fig. 2) at a degree greater than zero relative to the central axis. Note that the longitudinal axis of step 31 remains static as the distal end 22 is bent to form an angle in relation to the longitudinal axis of step 31.



Regarding claim 78, 90, 91, the guide wire is a material and of dimensions for retaining the bending of the distal portion in a curved configuration (col. 6, lines 52-56). The distal portion is manually bendable in a central minor plane when at least a part of the alignment portion is bent out of the central major plane because the distal portion is established as being made of a material that is flexible in multiple positions for navigation (col. 5, lines 56-61). Backman establishes the core wire 12, which includes the distal end 22, constructed of stainless steel (col. 4, line 56).

Regarding claims 79 and 80, 92, 93, the major surfaces of distal end 22 can be seen converging in Fig. 1 as the minor surfaces are remain parallel to each other.

Regarding claim 82, 95, the core wire 12 is seen as extending proximally from proximal end 14 to distal end 22 integrally as one piece (col. 4, lines 57-58) terminating at a distal end with hemispherical distal bulbous portion end 16.

Regarding claim 83, the guide wire comprises a sleeve 52/38 extending from and secured to the bulbous portion extending in proximal direction beyond the distal end 22, the core wire 12 extending through the sleeve. The sleeve terminates where it is secured to the core wire at 21 which is located intermediate the proximal and distal end of the guidewire. The sleeve is capable of being secured to the guide wire by soldering. The transverse cross-section of the sleeve coincides with the periphery of the transverse cross-section of the bulbous portion because they have the same transverse cross-section.

Regarding claim 84, the sleeve made of platinum (col. 57-60).

Regarding claim 86, the elongated guide wire is a guidewire 12 for accessing a remote site as established under the summary and objects of the invention of Backman.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 77, 85, 89, 96 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,957,865 to Backman et al. (Backman), as applied to claim 77 above, in view of EP 0 773 037 to Bostrom et al. (Bostrom) cited in the IDS.

Regarding claim 77, 89, 96 and 97 Backman discloses the limitations of the claims as stated above and that the distal rectangular end 22 may be bent into a specific angle chosen in accordance to a particular use (col. 6, lines 36-46). Backman does not expressly disclose where the angle is in the range of 30 to 90 degrees. Bostrom is a reference in analogous art that teaches a inner stylet having a non-circular cross-section (col. 3, lines 25-26) that is pre-bent to one side in a direction (col. 3, lines 36-40) that can cover an angle in the range of 30 to 90 degrees (col. 4, lines 19-24). One having an ordinary skill in the art at the time the invention was made would have found it obvious to modify the guidewire of Backman to comprise the pre-bent configuration in the range of 30 to 90 degrees of Bostrom as the predictable result of employing a guidewire within a body with a pre-bent configuration would ensue. Therefore, a skilled artisan would have found the combination of Backman and Bostrom obvious.

Regarding claim 85, Backman discloses where the sleeve is made up of a first longitudinal extending section comprising a tightly wound helical coil 52 and a second longitudinal extending section 38. Backman does not expressly disclose where the second longitudinal extending section is made of a plastic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the

second longitudinal extending section to be made of plastic since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736